K062579

2 **510(K) SUMMARY [AS REQUIRED BY 21 CFR 807.92(C)]**

NOV 2 8 2006

Submitter's Name / Contact Person

Manufacturer
RITA Medical Systems, Inc.
One Horizon Way
Manchester, Georgia 31816

Contact
David Smith
Director of Vascular Products Engineering
706-846-3126

General Information

Trade Name	OmniPICC P.I.		
Common Name	Peripherally Inserted Central Catheter (PICC), 4 French single and 5 French double lumen		
Classification Name	Percutaneous, implanted, long-term intravascular catheter Classification Number: 21 CFR §880.5970 Classification Panel: General Hospital Product Code: 80LJS		
Equivalent Device	**Product**	**Manufacturer**	**510(k) #**
	OmniPICC PI™ Catheter	RITA Medical Systems	K051102
	PowerPICC™ Catheter	Bard Access Systems, Inc	K033389, K050931, K051672, & K051991

Device Description: Other OmniPICC P.I product codes were cleared previously under 510(k) K051102.The purpose of this 510(k) is to add new codes in 4 French single and 5 French dual lumen sizes.

The Peripherally Inserted Central Catheter (OmniPICC P.I.) kit includes a catheter and introduction components. The catheter is a percutaneous central venous catheter inserted peripherally. The catheter is comprised of radiopaque polyurethane tubing. The catheter is attached to an injection molded polyurethane hub with extension leg(s) for access via a luer lock device. Each product is packaged in a sterile tray with appropriately sized introducer components. This PICC product line includes externally communicating central venous catheters of 60 cm that is trimmable from the distal end with a single 4 Fr single and 5 Fr dual lumen configurations. These are tested to withstand power injection of 3ml/sec (4 Fr Single) to 5 ml/sec at a maximum power injection setting of 300 psi.

In order to clearly identify the product as power inject able, and the rate to which it is power inject able, the following mechanisms are used:

- The device has "POWER INJECTABLE" printed on the extension legs.
- The device clamps contain ID inserts that have "300 PSI" printed on one side

- The device clamps contain ID inserts that have "3ml/sec" (4 Fr Single) or "5ml/sec" printed on the opposite side

Intended Use: The OmniPICC P.I. is intended to be used by medical professionals in patients who require either acute or long-term (chronic) peripheral central venous access for the infusion of medications, nutritional or other parenteral solutions, or blood products, and for the withdrawal of blood samples.

Indications for Use: The OmniPICCPI Peripherally Inserted Central Catheter is indicated for use in attaining short and long term vascular access for administration of medications, parenteral nutrition, IV fluids, blood products or blood withdrawal. The catheter may be inserted via the basilic, cephalic and medial veins of the upper extremity. The catheter is intended for implantation dwell time of shorter or greater than 30 days. The maximum recommended infusion rate is 3ml/sec to 5ml/sec. The maximum pressure or pounds per square inch (psi) of the power injector utilized should not exceed 300 psi.

Substantial Equivalence Comparison: The OmniPICC P.I. and its predicate, the Bard PowerPICC™, are identical in intended use and fundamental scientific technology. The two devices are substantially similar in configuration, dimensions, and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David Smith
Director of Vascular Products Engineering
Rita Medical Systems, Incorporated
One Horizon Way
Manchester, Georgia 31816

NOV 28 2006

Re: K062579
Trade/Device Name: OmniPICC P.I.
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: August 30, 2006
Received: September 12, 2006

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: OmniPICC P.I.

Indications For Use:

The OmniPICCPI Peripherally Inserted Central Catheter is indicated for use in attaining short and long term vascular access for administration of medications, parenteral nutrition, IV fluids, blood products or blood withdrawal. The OmniPICCPI is indicated for power injection of contrast media at a maximum recommended infusion rate of 3ml/sec to 5ml/sec and maximum pressure or pounds per square inch (psi) of 300 psi.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for ADW for CDR

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) K062579